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Supreme Court of the United States

OCTOBER TERM, 1969

No. 1436

CARTER-WALLACE, INC.,

Petitioner,

v.

ROBERT H. FINCH, SECRETARY OF HEALTH, EDUCATION AND WELFARE, and CHARLES EDWARDS, COMMISSIONER OF FOOD AND DRUGS,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

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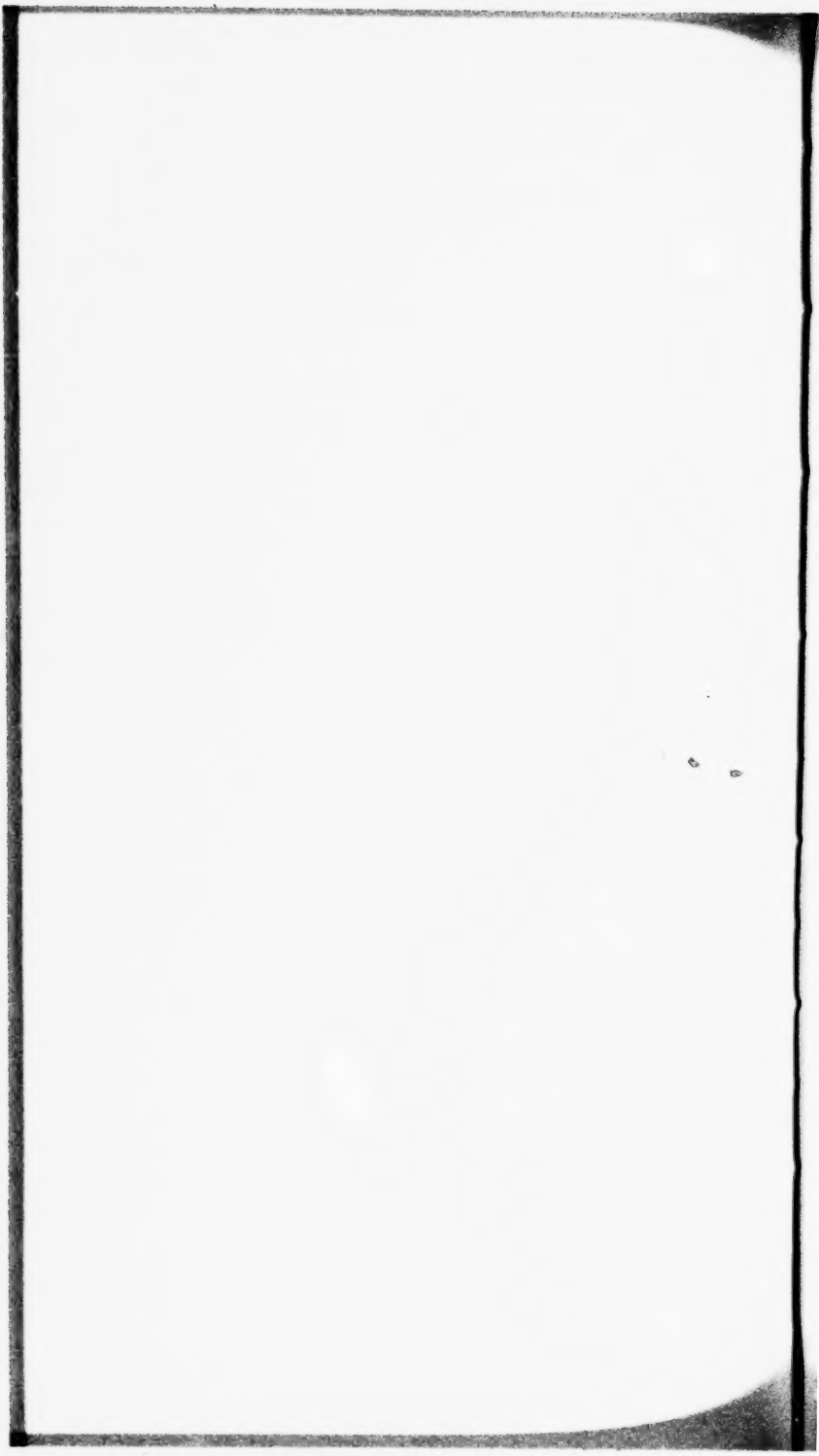

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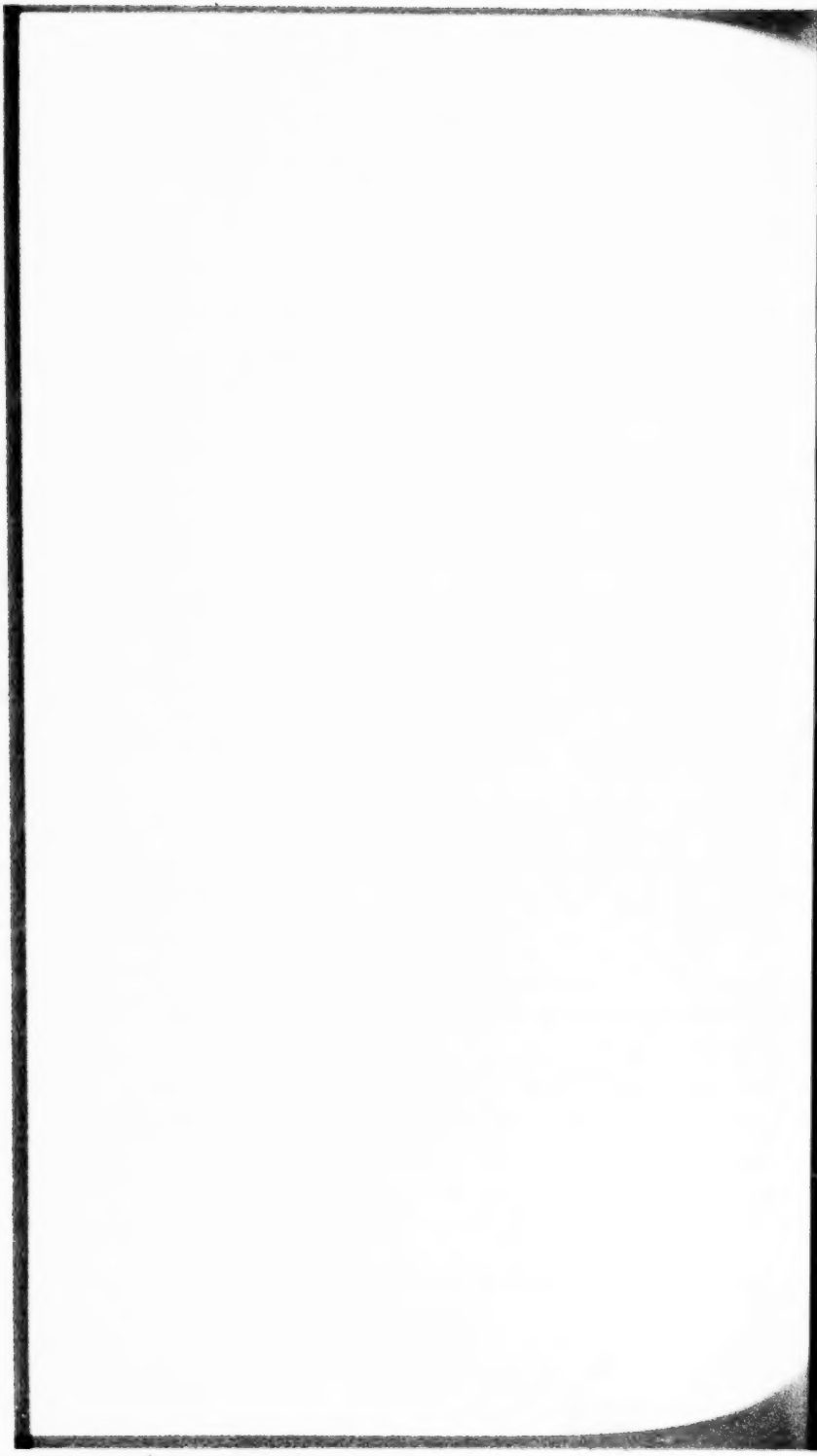

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ROBERT H. FINCH, SECRETARY OF HEALTH, EDUCATION AND WELFARE, and CHARLES EDWARDS, COMMISSIONER OF FOOD AND DRUGS,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

Petitioner, Carter-Wallace, Inc., prays that a writ of certiorari issue to review the decree and opinion of the United States Court of Appeals for the Fourth Circuit.

Opinions Below

The opinion of the Court of Appeals, reported at 417 F.2d 1086, is in Appendix A (p. 1a, *infra*). The opinion of the Hearing Examiner is in Appendix B (p. 20a). The Findings of Fact and Conclusions of Law of the Commissioner of Food and Drugs is in Appendix C (p. 35a).

Jurisdiction

The decree of the Court of Appeals for the Fourth Circuit was entered on November 25, 1969. On February 10, 1970, Mr. Chief Justice Burger extended the time for filing a petition for a writ of certiorari to and including April 21, 1970. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

Questions Presented

1) Whether an order of the Commissioner of Food and Drugs, which by statute "shall be based only on substantial evidence of record", can be sustained when the only support for such order is an unverified theory suggested by a single witness, which is in direct conflict with all the evidence in the record.

2) Whether there was proper adherence to "the whole record" requirement for judicial review of agency action.

3) Whether the statute compels the Commissioner to exempt the meprobamate combination products because the Examiner found that such products do not have a potential for abuse.

4) Whether the order as to the meprobamate combination products should be set aside on the ground that the Commissioner failed to make essential findings of fact as to such products.

Statutes and Regulations Involved

The relevant statutes and regulations are set forth in Appendix E (p. 68a).

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Statement

The basis for federal jurisdiction in the Court of Appeals is Sections 201(v) and 701(f) of the Federal Food, Drug, and Cosmetic Act, as amended (the "Act") (21 U.S.C. 321(v), 371(f)), and Section 10 of the Administrative Procedure Act (5 U.S.C. 702, 704, 706).

This is a proceeding to review an order of the Commissioner of Food and Drugs ("FDA"). The order would impose on the drug meprobamate the identical special controls and restrictions as are imposed on barbiturates ("goof balls"), amphetamines ("pep pills"), LSD and other known dangerous drugs. The order, promulgated after an evidentiary hearing, is under the amendments to the Act known as the "Drug Abuse Control Amendments of 1965" (the "Amendments") (79 Stat. 226, July 15, 1965).* The administrative hearing as to meprobamate was the first under the Amendments. This is the first case to review the scope and intended coverage of the Amendments and the validity of an FDA order thereunder. Because of the nature of the FDA findings at issue here, this case involves questions which are of utmost interest and importance to the scientific world.

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* FDA has stayed the order pending "a final judgment in the proceedings for judicial review" (33 F.R. 3635, 3/1/68). The controls imposed by the Amendments are accomplished by limiting the number and time in which prescriptions may be refilled, by requiring a drug abuse symbol on labels and other packaging to advise of the drug's abuse potential, by increased recordkeeping and inspection requirements, by regulation of intrastate traffic, and by making possession of the drug, other than by the user, illegal outside of legitimate channels of commerce (21 U.S.C. 360(a), 21 C.F.R. 166.18, H.R.Rep. No. 130, 89th Cong., 1st Sess., pp. 1, 3 (1965)).

A.

Meprobamate, a prescription drug, is classified as a "minor tranquilizer". It was developed by petitioner in 1952 and approved for sale by FDA in 1955. It rapidly became the most widely prescribed drug for the symptomatic relief of anxiety and tension. Petitioner markets meprobamate under the name "Miltown", and sells meprobamate to other pharmaceutical companies for resale under their own brand names.

The principal target of the Amendments was the amphetamines and barbiturates, which had demonstrated a substantial abuse potential because of their effects on the central nervous system. Not all drugs and not all drug abuse are covered or intended to be covered by the Amendments. Nor does it suffice merely to show a drug has a depressent, stimulant or hallucinogenic effect on the central nervous system. A drug can be listed only if it is found to have, in the words of Section 201(v)(3) of the Amendments, "a potential for abuse *because* of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect" (21 U.S.C. 321(v)(3)).* The need to prove a causal relationship between a drug's abuse potential and its effect on the central nervous system was stressed throughout the legislative history of the Amendments. The House Report** stated that "a drug's 'potential for abuse' should be determined on the basis of its having been demonstrated to have such depressant or stimulant effect on the central nervous system as to make it reasonable to assume there is a substantial potential" for abuse. The Senate Report*** also

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* Unless otherwise noted, italics have been supplied.

** Report of the Committee on Interstate and Foreign Commerce on H.R. 2 (H.Rept. No. 130, 89th Cong., 1st Sess., p. 7).

*** Report of the Committee on Labor and Public Welfare To Accompany H.R. 2 (S.Rept. No. 337, 89th Cong., 1st Sess., p. 5).

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emphasized that the Amendments apply only to drugs which have a substantial abuse potential "because of their depressant or stimulant effect on the central nervous system".

Congress considered the causal relation question of such importance, that it authorized FDA to appoint an independent "committee of experts to advise" on two matters, namely, "(A) whether or not the substance involved has a depressant or stimulant effect on the central nervous system or a hallucinogenic effect", and "(B) *whether the substance involved has a potential for abuse because of its depressant or stimulant effect on the central nervous system*" (21 U.S.C. 360(a)(g)(1)).*

Petitioner and FDA approached the case very differently. Petitioner acknowledged that meprobamate has a selective central nervous system depressant effect, and, like all ingestible substances, has some potential for abuse. The thrust of its case was that meprobamate's central nervous system depressant effect is in no way responsible for or related to its abuse or potential for abuse. Petitioner's medical witnesses, including top-level Government physicians and public health service officials, testified from carefully controlled animal experiments and clinical studies that meprobamate's selective depressant action on the central nervous system cannot possibly contribute to, much less be the cause of, its potential for abuse.

The evidence overwhelmingly demonstrated that the rare incidents of excessive use or other abuse of meprobamate

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* Though FDA appointed an independent committee of experts to consider meprobamate, neither the report of that committee nor its deliberations were introduced at the hearing. After objection to the introduction of a bare summary of the report was sustained, FDA withdrew the summary and moved "that the questions and answers relating to the advisory committee be stricken from the record" (TR. 343).

are not a result of the drug's pharmacological action on the central nervous system. When meprobamate is abused it is for the same reason and by the same type individual who would abuse any number of other ingestible substances which have absolutely no effect on the central nervous system. Quite apart and distinct from the drug addict, who abuses a drug to achieve certain definite non-therapeutic effects, there is another though far smaller group who abuse vitamins, aspirin, candy and virtually any other substance, though there may be no effect, or even a wholly unpleasurable one (TR. 3434-35, App. 514).* In the House hearings on the Amendments, it was pointed out that every drug, and indeed, "Anything that the human body consumes", has some abuse potential.** But Congress emphasized that this was not the type of abuse at which the Amendments were directed. The Amendments were aimed at the drugs which, because of their action on the central nervous system, furnish "kicks", "thrills" or other non-therapeutic effects sought by drug abusers.

FDA did not even attempt to establish a connection between meprobamate abuse and its central nervous system depressant effect. Instead, FDA promulgated a regulation which conclusively presumed that if meprobamate had a potential for abuse, such potential results from its central nervous system depressant effect (p. 77a). Accordingly, FDA concentrated on proving that meprobamate has an abuse potential, ignoring the cause and effect test of the Amendments. FDA called more than 20 physician witnesses on its direct case, but failed to elicit a single

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* References to "TR." are to the original Transcript of the hearing. References to "App." are to the Appendix to Petitioner's Brief printed for use in the Court of Appeals.

** Hearings Before Committee on Interstate and Foreign Commerce of the House of Representatives, 89th Cong., 1st Sess., on H.R. 2, p. 151.

opinion as to whether meprobamate's abuse potential was because of its central nervous system depressant effect. More than 100 medical articles were evidenced by FDA, but none were related to the cause and effect question.

Armed with the regulatory presumption, FDA counsel said "the regulations * * * would apply in this hearing, * * * and FDA would introduce at this hearing evidence under" the regulations (App. 137). FDA reiterated that the "sole issue * * * [is] whether meprobamate is a drug with a potential for abuse" (TR. 1684-85); and that "it is the Government's position that the issue at this trial and this hearing is, does meprobamate have a potential for abuse" (TR. 2495), totally disregarding the need to prove that such potential for abuse is "because of its depressant * * * effect on the central nervous system" (21 U.S.C. 321(v)(3)).

The FDA Examiner also deemed the regulatory presumption to control. He admitted petitioner's evidence that there was no causal relationship between meprobamate abuse and its depressant effect on the central nervous system only to provide "the necessary record to advance this argument" to "a reviewing court", and "to avoid a remand * * * to take evidence on this point" (App. 357, TR. 1974).

Accordingly, it could not be clearer that throughout the hearing, both FDA counsel and the FDA Examiner firmly believed and proceeded on the basis that FDA need prove only that meprobamate had a potential for abuse, without even attempting to satisfy the cause and effect test of the Amendments. In fact, neither the Examiner's proposed findings of fact, dated 4 months after the close of the hearing (App. 49), nor the Commissioner's initial findings of fact, dated 7 months after the hearing (App. 79), contained a finding on the causal-relationship question. It was not until well over a year after the hearing

had concluded, and only after receipt of petitioner's objections to the proposed findings of fact, did FDA expressly find that meprobamate had a potential for abuse because of its depressant effect on the central nervous system (p. 61a).

The cause and effect question was one of the key issues on appeal. The Court rejected FDA's position that meprobamate could be controlled under the Amendments on the mere showing that the drug had an abuse potential. The Court recognized that "to subject meprobamate to the Act's special controls the Commissioner must find" that it has a substantial potential for significant abuse, and "that this potential results from its depressant effect on the central nervous system" (pp. 4a, 8a). The Court further agreed that FDA's regulation and its conclusive presumption "cannot be used to dispense with proof of the causal relationship required by the statute. *Miller* v. *United States*, 294 U.S. 435, 440 (1935)" (p. 9a).

Though FDA had called over 30 witnesses and had evidenced thousands of pages of scientific exhibits in the course of a three-month hearing, the Court could find neither "direct evidence" nor even any "verified theories" (p. 12a) to support the alleged causal relationship. On the other hand, as the Court noted, a "number of well-qualified medical witnesses" testified that there was "no relation between meprobamate's potential for abuse and its depressant effect on the central nervous system" (pp. 6a, 11a).

Nevertheless, the Court held the causal relationship finding was supported by substantial evidence. The "evidence" on which the Court relied consisted of a "theory", which "had not yet been verified", which if ever verified, would relate to the barbiturates and not to meprobamate, which was suggested as a possibility by but one of a total of 50 physician witnesses heard at the hearing, and which was

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in direct conflict with the results of controlled studies and clinical observation by a number of eminent physicians.

The theory was suggested by Dr. Jerome Jaffe, a psychiatrist with extensive experience with the use and effects of barbiturates, but without any comparable expertise as to meprobamate.* He testified that physical dependence on barbiturates may result from changes in the subcortical region of the brain caused by the central nervous system depressant effect of barbiturates. Dr. Jaffe stressed that this was only a theory, and, as the opinion below states, "Emphasizing that his theory of barbiturate dependence had not yet been verified, he suggested that if it is valid for barbiturates, it may be equally valid for meprobamate" (p. 13a).**

The Court of Appeals seemed more impressed with FDA's contention as to the difficulties in establishing the required causal relationship than it was with the alleged evidence of such relationship. For the Court concluded (p. 14a):

> "[*T*]*aking into account our imperfect knowledge of how drugs injure people,* we hold that substantial evi-

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*Dr. Jaffe had not conducted any studies or experiments with meprobamate, controlled or otherwise. On the clinical level, he did not have "the faintest idea" as to the extent of meprobamate abuse (TR. 476). Actually, he knew of only "one case of a patient starting on meprobamate, and then going on to abuse that drug" (TR. 467).

**The Court's only other reference to the alleged causal relationship was with respect to "euphoria", stating that "no evidence was introduced that euphoria results from any effect other than the action of depressant or stimulant drugs on the central nervous system" (pp. 13a-14a). Since there was absolutely no evidence that meprobamate's central nervous system depressant effect caused euphoria, there was no purpose in disproving a contention which FDA was not even making. On the contrary, Dr. Jaffe, FDA's key witness, testified "that nobody knows the mechanism of action of euphoria" (App. 243). FDA's post-hearing memorandum conceded that "euphoria induced by * * * opiates or cocaine [both central nervous system depressants] does not involve depression of the neocortex."

dence supports the Commissioner's finding of a causal relation between meprobamate's depressant effect upon the central nervous system and its potential for abuse."

B.

Petitioner manufactures five meprobamate combination products, "which consist of meprobamate combined with other drugs" (p. 39a). FDA framed the issues so the hearing would cover both meprobamate and the combination products. Petitioner established and the Examiner found (p. 33a):

> "There is a lack of substantial evidence in this record that meprobamate combined with other drugs, manufactured by either respondent or others, have a substantial potential for significant abuse."

The Commissioner made no findings on the combination products. He concluded that combination products are governed by Section 201(v)(3) of the Amendments (21 U.S.C. 321(v)(3)), and all drugs containing any quantity of meprobamate are "depressant or stimulant drugs" by operation of law, and, as such, are subject to the controls of the Amendments. The Court of Appeals agreed (p. 16a).

It is petitioner's position that combination products are governed by Section 511 (f)(2)(B), which provides that FDA *"shall"* exempt any combination product which contains another substance "not having a depressant or stimulant effect on the central nervous system", and which is present in sufficient concentration to prevent the finished drug from having "a potential for abuse" (21 U.S.C. 360(a)(f)(2)(B)). By using "shall" instead of "may", Congress made plain that the exemption is mandatory, and FDA has no discretion once it is found that the finished product does not have an abuse potential. In short, a combination prod-

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uct must be judged by the abuse potential of the finished product, not by a single one of its ingredients.*

Despite the fact the meprobamate combination products were a separate issue at the hearing, and the Examiner affirmatively found such products do not have a potential for abuse, the Court held that the Commissioner's failure to make an affirmative finding of fact as to such products meant that petitioner must initiate an entirely new proceeding for their exemption from the Amendments.

Reasons for Granting the Writ

I.

The opinion below will have important and far-reaching effects on virtually every case involving review of agency action under the "substantial evidence" rule. If, as the Court of Appeals in effect held, the substantial evidence requirement is satisfied by a suggested theory which "had not yet been verified", and which was in direct conflict with the unequivocal and unimpeached testimony of recognized experts, then the substantial evidence rule would become a nullity. It is difficult to conceive of any case in which an agency could not point at least to an unverified theory to support its findings.

It is anomalous and unfortunate that the substantial evidence rule was misapplied in this particular case. Since this was the first occasion in which any governmental body had attempted to determine a drug's potential for abuse, and more important, the pharmacological cause if any for such abuse potential, this case has been and is of vital

* It was established that each of the meprobamate combination products contains another substance which does not have a depressant or stimulant effect on the central nervous system and which is present in sufficient concentration to prevent the finished product from having a potential for abuse (App. 362-63).

concern to a large segment of the medical and scientific community. As one physician at the hearing put it, the mere listing of meprobamate under the same law and bearing the same drug abuse symbol as LSD, goof balls and pep pills, would "produce a catastrophe in American medicine." (TR. 3167). Because of the importance of the scientific questions involved, and because FDA has no expertise of its own in this new area of pharmacology, strict adherence to the substantial evidence rule is especially warranted. This is not a case which should or need be decided by speculation or theory, though the Court below seemed to believe an unverified theory should suffice here "because present medical knowledge has no definitive explanation" for the cause of drug abuse (p. 12a). Such statement disregards the competent and uncontradicted evidence that drug abuse, as that term is used in the Amendments, is caused by drugs which generate certain non-therapeutic effects because of their action on the central nervous system. Meprobamate is not one of those drugs, and there is not a scrap of evidence in the record to the contrary.

Significantly, Dr. Jaffe, the FDA witness on whom the Court relied, demonstrated his concern that his testimony not be misinterpreted. He repeatedly emphasized that his testimony was only a "theory"; "There are a number of theories" on this point (App. 232); "There are a number of studies now under way attempting to verify or refute the theory" (App. 236); and that his "theory tends to encompass [another] theory" (App. 240).*

* After receipt of FDA's proposed findings, which were printed in the Federal Register and circulated by FDA to physicians across the country, Dr. Jaffe wrote the Commissioner to express his concern that his "testimony is being used by FDA—not for the purpose of stating a theory, which was all that was ever intended—but as support for a so-called finding of fact that withdrawal reactions after cessation of meprobamate and tolerance to that drug are definitely due to its central nervous system depressant effect."

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By accepting such wholly theoretical testimony as "substantial evidence", the Court deviated significantly from "the usual rule that evidence * * * by a medical man that a necessary fact is 'possible' or 'conceivable' or 'may be' is not sufficient" (Jaffe, Judicial Control of Administrative Action, p. 598, fn. 6); "Where the opinion of the expert rests upon theories as to which there is no substantial agreement, and is in fact a mere sequence of conjectures, it is of no probative value" (Rogers, Expert Testimony, §135, p. 314 (3rd ed., 1941)); testimony of "a speculative and uncertain nature can afford little, if any, support to findings based thereon" (*Kidder Oil Co.* v. *F.T.C.*, 117 F.2d 892, 899 (7th Cir., 1941)).

The opinion of the Court of Appeals is also in conflict with applicable decisions of this Court, that "Substantial evidence is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Edison Co.* v. *Labor Board*, 305 U.S. 197, 229 (1938). And, as held in *Labor Board* v. *Columbian Co.*, 306 U.S. 292, 300 (1939), substantial evidence "must do more than [merely] create a suspicion of the existence of the fact to be established".

Nor did the Court of Appeals follow "the whole record" requirement for judicial review of agency action (5 U.S.C. 556(d)). Though the Court's opinion notes that a number of well-qualified medical witnesses testified, without challenge or contradiction, that meprobamate's central nervous system depressant effect had no relation to its abuse potential, such testimony was disregarded in favor of a theory

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Dr. Jaffe reiterated that he did "not believe there is medical evidence which 'establishes' that 'meprobamate's potential for abuse results from its effect of depression on the central nervous system' ". Dr. Jaffe's letter is reprinted in the Annex to petitioner's Reply Brief below.

suggested by a single witness. Pertinent is *Universal Camera Corp.* v. *N.L.R.B.*, 340 U.S. 474, 487-88 (1951):

> "Whether or not it was ever permissible * * * to determine the substantiality of evidence supporting a * * * decision merely on the basis of evidence which in and of itself justified it, without taking into account contradictory evidence or evidence from which conflicting inferences could be drawn, the new legislation definitively precludes such a theory of review and bars its practice. The substantiality of evidence must take into account whatever in the record fairly detracts from its weight. This is clearly the significance of the requirement * * * that courts consider the whole record."

The foregoing applies *a fortiori*, since not only did the Court fail to take into account petitioner's evidence, but there was no evidence on the other side "which in and of itself justified" the causal relationship finding. The "assurance of a desirable flexibility in administrative procedure does not go so far as to justify orders without a basis in evidence having rational probative force." (*Edison Co.* v. *Labor Board, supra*, p. 230). That principle should be particularly unyielding where, as here, the administrative determination would have significance far beyond the confines of this one case.

II.

As to the meprobamate combination products, the Court of Appeals held (p. 16a):

> "In this hearing the government was required to show only that meprobamate satisfied the Act's definition of a depressant drug and that the combination drugs contained meprobamate. *Lack of evidence con-*

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cerning the effect of the combination drugs cannot be substituted for the affirmative findings required for exemption."

This misses the mark, for the Examiner did affirmatively find that the meprobamate combination products do not have a potential for abuse (p. 33a).

It is true the Commissioner did not adopt that finding, but neither did he reject it. He made no finding of fact as to the meprobamate combination products—an omission which, instead of prejudicing petitioner and requiring an entirely new hearing as to such products, is itself ground for reversal.

FDA framed the issues for the hearing so as to plainly include not only meprobamate, but the combination "drugs containing meprobamate" (App. 113). The Examiner ruled that petitioner's separate evidence as to the combination products "is within our case" (App. 359). Once the Examiner found from the evidence that the meprobamate combination products do not have an abuse potential within the meaning of the Amendments, the Commissioner had to do one of two things. If he agreed with that finding, the combination products had to be exempted from the Amendments as a matter of law (21 U.S.C. 360 (a)(f)(2)(B)). If he disagreed, then he had to promulgate a new finding of fact which petitioner could challenge for lack of substantial evidence.

In no event can the Comissioner's failure to make a finding of fact serve as basis for controlling the combination products. On the contrary, "In the absence of a finding of essential basic facts, the order cannot be sustained" *Atchison Ry. Co.* v. *United States,* 295 U.S. 193, 202 (1935).

This Court has "repeatedly emphasized the need for • • • basic or essential findings on which administrative

orders rest." *Colorado-Wyoming Gas Co.* v. *F.P.C.*, 324 U.S. 626, 634 (1945); *Securities and Exchange Commission* v. *Chenery Corp.*, 318 U.S. 80, 96 (1943); *United States* v. *Carolina Carriers Corp.*, 315 U.S. 475, 489 (1942); *Florida* v. *United States*, 282 U.S. 194, 212, 215 (1931).

It is now fundamental that where basic findings are lacking, the reviewing court will not search the record for evidence to support the agency's decision:

> "In the absence of such findings, we are not called upon to examine the evidence in order to resolve opposing contentions as to what it shows or to spell out and state such conclusions of fact as it may permit. The Commission is the fact-finding body and the Court examines the evidence not to make findings for the Commission but to ascertain whether its findings are properly supported" (*Florida* v. *United States, supra*, p. 215).

The meprobamate combination products were the subject of an exhaustive administrative hearing. If such products can be controlled under the Amendments merely by reason of the control of the meprobamate ingredient, then Section 360 (a)(f)(2)(B), which is specifically directed at the combination products, is rendered totally meaningless.

It bears reiteration that this is the first case to involve an interpretation of the Drug Abuse Control Amendments. The application of the Amendments to combination products is particularly important, since more and more pharmaceutical companies are developing combination products which contain ingredients in such quantity or proportion as to effectively preclude the possibility of abusing the finished product. Future administration of the Amendments will be greatly facilitated by a definitive interpretation of their scope and coverage by this Court.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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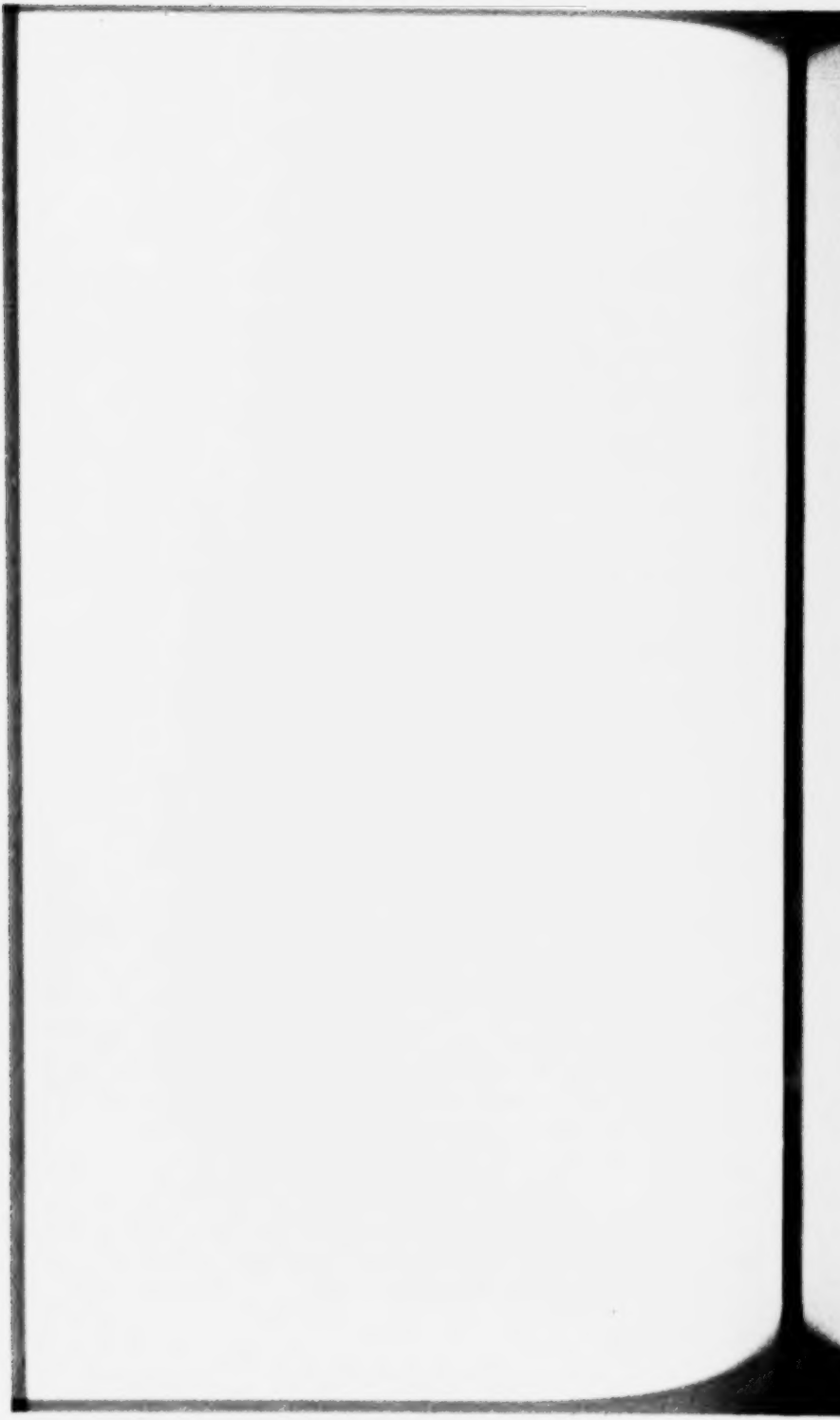

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